

(2) *Packaging.* The immediate container shall be of colorless, transparent glass and it shall be a tight container as defined by the U.S.P. It shall be so sealed that the contents cannot be used without destroying such seal. It shall be of appropriate size to permit the addition of 20 milliliters of sterile diluent when preparing a stock solution for use in making further dilutions for microbial susceptibility testing.

(3) *Labeling.* In addition to the requirements of § 432.5(a)(3) of this chapter, each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On its outside wrapper or container and on the immediate container:

(a) The statement "For laboratory diagnostic use only".

(b) The statement "Sterile".

(c) The batch mark.

(d) The number of units of penicillin G in each immediate container.

(ii) On the circular or other labeling within or attached to the package, adequate information for use of the drug in the clinical laboratory.

(4) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The penicillin G used in making the batch for potency, moisture, pH, and crystallinity.

(b) The batch for potency, sterility, loss on drying, and pH.

(ii) Samples required:

(a) The potassium penicillin G used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch:

(1) For all tests except sterility: A minimum of 20 immediate containers.

(2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay—(1) Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Reconstitute as directed in the labeling. Dilute an aliquot with 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to the prescribed reference concentration.

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the meth-

od described in paragraph (e) (1) or (2) of that section, except if using the method in paragraph (e)(2), use medium B in lieu of medium A.

(3) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using the drug reconstituted as directed in the labeling.

§ 460.79 Polymyxin B sulfate diagnostic sensitivity powder.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Polymyxin B sulfate diagnostic sensitivity powder is polymyxin B sulfate, with or without one or more suitable buffers and diluents, packaged in vials and intended for use in clinical laboratories for determining in vitro the sensitivity of microorganisms to polymyxin B. Each vial contains the equivalent of 20,000 units of polymyxin B. The potency of each immediate container is satisfactory if it contains not less than 90 percent and not more than 115 percent of its labeled content. It is sterile. Its loss on drying is not more than 7.0 percent. When reconstituted as directed in the labeling, its pH is not less than 5.0 and not more than 7.5. The polymyxin B sulfate used conforms to the standards prescribed by § 448.30a(a)(1) (i), (v), (vi), and (ix) of this chapter. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(2) *Packaging.* The immediate container shall be of colorless, transparent glass and it shall be a tight container as defined by the U.S.P. It shall be so sealed that the contents cannot be used without destroying such seal. It shall be of appropriate size to permit the addition of 20 milliliters of sterile diluent when preparing a stock solution for use in making further dilutions for microbial susceptibility testing.

(3) *Labeling.* In addition to the requirements of § 432.5(a)(3) of this chapter, each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On its outside wrapper or container and on the immediate container:

(a) The statement "For laboratory diagnostic use only".

- (b) The statement "Sterile".
- (c) The batch mark.
- (d) The number of units of polymyxin B in each immediate container.
- (ii) On the circular or other labeling within or attached to the package, adequate information for use of the drug in the clinical laboratory.
- (4) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:
 - (i) Results of tests and assays on:
 - (a) The polymyxin B sulfate used in making the batch for potency, moisture, pH, and identity.
 - (b) The batch for potency, sterility, loss on drying, and pH.
 - (ii) Samples required:
 - (a) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.
 - (b) The batch:
 - (1) For all tests except sterility: A minimum of 20 immediate containers.
 - (2) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.
- (b) *Tests and methods of assay—(1) Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Reconstitute as directed in the labeling. Dilute an aliquot with 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the prescribed reference concentration.
- (2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(1) of that section.
- (3) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.
- (4) *pH.* Proceed as directed in § 436.202 of this chapter, using the drug reconstituted as directed in the labeling.

§ 460.86 Spectinomycin hydrochloride powder for microbial susceptibility testing.

- (a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Spectinomycin hydrochloride powder for microbial susceptibility testing is spectinomycin dihydrochloride pentahydrate with or without one or more suitable buffers and diluents, packaged in vials and intended for use in clinical laboratories

for determining in vitro the susceptibility of microorganisms to spectinomycin. Each vial contains spectinomycin hydrochloride equivalent to 100 milligrams of spectinomycin. The potency of each immediate container is satisfactory if it contains not less than 90 percent and not more than 115 percent of its labeled content. It is sterile. Its moisture content is not more than 8 percent. When reconstituted as directed in the labeling, its pH is not less than 3.8 nor more than 5.6. The spectinomycin hydrochloride used conforms to the standards prescribed by § 455.80a(a)(1) (i), (ii), (vii), (viii), (ix), (x), and (xi) of this chapter.

(2) *Packaging.* The immediate container shall be of colorless, transparent glass and it shall be a tight container as defined by the U.S.P. It shall be so sealed that the contents cannot be used without destroying such seal. It shall be of appropriate size to permit the addition of the amount of sterile diluent prescribed in the labeling when preparing a stock solution for use in making further dilutions for microbial susceptibility testing.

(3) *Labeling.* In addition to the requirements of § 432.5(a)(3) of this chapter, each package shall bear on its label or labeling, as hereinafter indicated, the following:

- (i) On its outside wrapper or container and on the immediate container:
 - (a) The statement, "For laboratory use only".
 - (b) The statement, "Sterile".
 - (c) The batch mark.
 - (d) The number of milligrams of spectinomycin in each immediate container.

(ii) On the circular or other labeling within or attached to the package, adequate information for use of the drug in the clinical laboratory.

(4) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

- (i) Results of tests and assays on:
 - (a) The spectinomycin hydrochloride used in making the batch for spectinomycin content, microbiological activity, moisture, pH, identity, residue on ignition, and crystallinity.